



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/616,511	07/10/2003	Bernd Misselwitz	SCH-1911	1752

23599 7590 10/06/2006

MILLEN, WHITE, ZELANO & BRANIGAN, P.C.
2200 CLARENDON BLVD.
SUITE 1400
ARLINGTON, VA 22201

EXAMINER

JONES, DAMERON LEVEST

ART UNIT PAPER NUMBER

1618

DATE MAILED: 10/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/616,511

Applicant(s)

MISSELWITZ ET AL.

Examiner

D. L. Jones

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

CLARIFICATION OF RECORD

1. The following office action is deemed necessary in light of Applicant's written request for a pre-appeal conference on 8/21/06 and the outcome of the conference.

RESPONSE TO APPLICANT'S ARGUMENTS

2. The Applicant's arguments filed 8/21/06 to the rejection of the claims made by the Examiner under obviousness type double patenting have been fully considered and deemed non-persuasive for the reasons set forth below.

Double Patenting Rejections

I. The provision rejection of claims 1 and 30 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 51 of copending application number 10/857,877 is MAINTAINED for reasons of record in the office action mailed 5/19/06 and those set forth below

Applicant asserts that the instant invention is distinguished over the cited prior art rejection because the claims are directed to thrombi imaging not visualizing plaque, infarcted tissue, or necrotic tissue.

Applicant's arguments are not found persuasive because both sets of claims are drawn to methods of using the same perfluoroalkyl containing complexes. Also, the species set forth in the patented invention are directly within the scope of the genus of claims 1-7 of the present application.

II. The rejection of claims 1-29 and 45-49 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-35 of US

Art Unit: 1618

Patent No. 6,818,203 is MAINTAINED for reasons of record in the office action mailed 5/19/06 and those set forth below

Applicant asserts that the instant invention is distinguished over the cited prior art rejection because the claims are directed to thrombi imaging not visualizing plaque, infarcted tissue, or necrotic tissue.

Applicant's arguments are not found persuasive because both sets of claims are drawn to methods of using the same perfluoroalkyl containing complexes. Also, the species set forth in the patented invention are directly within the scope of the genus of claims 1-7 of the present application

NEW GROUNDS OF REJECTION

101 Rejections

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 1-50 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

112 Rejections

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

Art Unit: 1618

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-50 provides for a method of imaging thrombi, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

103 Rejections

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-11 and 45-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Platzek (WO 97/26017).

Platzek discloses methods of MRI comprising administering perfluoroalkyl substituted metal complexes (see entire document, especially, abstract). The complexes have the formula as set forth in claim 1 which is the same as those of claims 8-11 of the instant invention. Since these complexes are the same as those set forth in

Art Unit: 1618

claims 8-11, they must inherently have the same functional properties as those claimed (i.e., as in claims 1-7 of the instant invention) since the same compounds must have the same properties. Applicant admits the compounds in claims 8-11 are the same as set forth in WO 97/26017, see page 8, fourth complete paragraph,. Also, these complexes include substitution encompassed by 'hydrophlic group' (e.g., due to hydroxyl, etc. substitution). Platzek discloses that the complexes may be used to mage various tissues, such as vascular tissues, ischemic tissues, infarctions, lymph tissues, etc. (columns 2-3). Platzek discloses that the complexes are extremely well suited for imaging the vascular diseases since they disperse therein after administration (column 2, lines 45+). These are the same tissues which are being claimed by Applicant.

While Platzek fails to specifically disclose that the methods of imaging are used for thrombi, it would have been obvious to one of ordinary skill in the art to employ the methods of Platzek for thrombi because Platzek discloses that his methods are suited for imaging vascular diseases and since thrombi is blood clots that are usually located in a blood vessel or a chamber of the heart a skilled practitioner in the art would recognize that the method of Platzek would also result in the detection of thrombi.

8. Claims 1-7, 12-29, and 45-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Platzek (WO 99/01161).

Platzek discloses methods of imaging comprising administering perfluoralkyl substituted metal complexes (see entire document, especially, abstract). The complexes have the formula as set forth in columns 2+, which is the same as set forth in

Art Unit: 1618

claims 12-29 of the present application. Since these complexes are the same as those set forth in claims 12-29, they must inherently have the same functional properties as those set forth in claims 1-7 of the instating invention because the same compounds must have the same properties. Applicant admits the compounds in claims 12-29 are the same as set forth in WO 99/01161, see page 8, last paragraph of Applicant's disclosure. Also, these complexes include substitution encompassed by 'hydrophilic group' (e.g., due to hydroxyl, etc. substitution). Platzek discloses that the complexes may be used for imaging various tissues, such as vascular tissues, ischemic tissues, infarctions, lymph tissues, etc. (columns 3-4). Platzek discloses that the complexes are well suited for imaging the vascular diseases since they disperse therein after administration (columns 3-4, bridging paragraph). These are the same tissues which are being claimed by Applicant.

While Platzek fails to specifically disclose that the methods of imaging are used for thrombi, it would have been obvious to one of ordinary skill in the art to employ the methods of Platzek for thrombi because Platzek discloses that his methods are suited for imaging vascular diseases and since thrombi is blood clots that are usually located in a blood vessel or a chamber of the heart a skilled practitioner in the art would recognize that the method of Platzek would also result in the detection of thrombi.

PRIORITY DOCUMENT

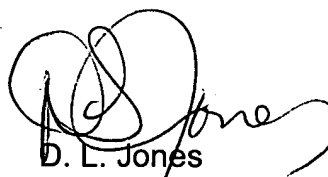
9. Receipt of the priority document filed 2/28/06 is acknowledged. The document was submitted under 35 U.S.C. 119(a)-(d), which papers have been placed in the file.

Art Unit: 1618

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



D. L. Jones
Primary Examiner
Art Unit 1618

September 29, 2006